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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,070	10/15/2003	Henrik Hansen	10177-232	8917
20583	7590	05/06/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,070	HANSEN, HENRIK	
	Examiner	Art Unit	
	Jennifer K Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 April 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-16, 18 and 19 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/15/2003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Examiner notes Applicant's election, without traverse, of Group I, claims 1-16 and 18-19.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-16 and 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,669,980. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application's claims are merely broader than the patent's claims. Additionally, claims 1 and 13 of the application are the same, in combination, as claim 1 of the patent.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10, 12, 15-16, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (US 6,355,058 B1) in view of Escallon et al. (US 4,749,125) and Cobbs, Jr. et al. (US 4,505,957).

Regarding claims 1 and 18, Pacetti et al. teach coating a stent with a polymer binder using electrostatic liquid spraying (abstract; col. 4, lines 4-5; paragraph bridging columns 5 and 6).

What Pacetti fails to teach is the type of apparatus used when performing electrostatic liquid spraying.

Escallon is cited for teaching an apparatus for electrostatic liquid spraying. Escallon teaches a nozzle apparatus for electrically charging and dispensing fluids and other flowable materials, comprising a fluid reservoir and housing, such that the reservoir communicates with a coating fluid chamber. The fluid is connected to a high voltage source (abstract) and is electrostatically charged for dispensation in small droplets (col. 1, line 13; col. 8, lines 20-21). Escallon teaches that the substrate is not limited in type and may be metallic or plastic, such as a loose object, and may be grounded (col. 8, lines 30-31 and 36). Escallon teaches that the coating fluid is not limited and that only

ionized water-based materials are inoperative (col. 8, line 47). As an example only, Escallon teaches one type of coating material to be an adhesive (col. 9, line 39). Examiner notes that adhesives for application to paper are polymers in solvent.

Since Pacetti teaches electrostatic liquid spraying a stent with polymer and Escallon teaches an apparatus for electrostatically liquid spraying polymers in solvents onto metal or polymer substrates, Escallon would have reasonably suggested the use of his apparatus in the method of Pacetti. It would have been obvious to one of ordinary skill in the art to use the teachings of Escallon in the method of Pacetti to provide Pacetti with an appropriate apparatus for electrostatic liquid spraying on a stent with the expectation of successful results because Escallon teaches application of solvent-based polymers onto metal or plastic loose objects. Stents are loose objects made of metal or plastic, thus falling into the category of substrates coatable by the apparatus of Escallon.

It is Examiner's position that Pacetti's teachings of "electrostatic liquid spraying" of polymer binder onto a stent inherently requires the polymer to be provided in a solvent. This is especially evident because Pacetti does not teach application of the polymer as a hot-melt. Since the polymers listed by Pacetti are solid at room temperature, application in liquid form would require the use of a solvent. Furthermore, Examiner notes that polymer in hot-melt form would not operate properly when coating a stent, as bridging would occur between the struts.

However, Examiner cites the following reference to teach the inherency of her position:

Cobbs teaches that electrostatic liquid spray-coating techniques are employed for coating normally liquid materials, i.e., paints or solvent coatings, in which it is practice to dissolve a film-forming solid in an organic solvent for deposition (col. 1, lines 34-45).

Regarding claims 2-3, Escallon teaches that the nozzle apparatus has an electrode conductor for charging the coating formulation by connection to the voltage source (see above and paragraph bridging columns 7 and 8).

Regarding claims 4-5, it is Examiner's position that duplicating the application step would have been obvious to one of ordinary skill in the art desiring to thicken the coating applied to the stent. In general, the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat. App. 1959).

Regarding claims 6 and 19, Pacetti teaches inclusion of radiopaque agents and therapeutic agents in the composition (col. 6, line 20).

Regarding claims 7-10 and 15-16, it is Examiner's position that selection of flow rate, resistivity, viscosity, and concentration of the coating composition, along with voltage and current used in the coating apparatus would have been obvious to one of ordinary

skill in the art. Given the product limitations of the coating apparatus, one of ordinary skill in the art would have selected the type, properties, and concentration of the polymers and solvents used in the coating composition for efficient operation in the coating apparatus. Also, given the type of polymers and solvents used and the type of substrate to be coated, one of ordinary skill in the art would have selected voltage and other power settings on the apparatus for efficient operation. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Because the materials of Applicant are the same or overlap those of Pacetti, the melting point requirements of Applicant would have been inherent.

In regard to claim 12, Pacetti teaches the use of polyglycolic acid for coating stents (claim 11).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tseng et al. is cited for teaching electrostatically coating a prosthesis while the substrate is grounded.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 571-

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272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
May 3, 2004